



US011324507B2

(12) **United States Patent**
Aravalli

(10) **Patent No.:** **US 11,324,507 B2**
(45) **Date of Patent:** **May 10, 2022**

(54) **DEVICE AND METHOD FOR ATTACHMENT OF A STOMAL SLEEVE**

- (71) Applicant: **Covidien LP**, Mansfield, MA (US)
- (72) Inventor: **AVVLN Srinivasa Murthy Aravalli**, Hyderabad (IN)
- (73) Assignee: **COVIDIEN LP**, Mansfield, MA (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 431 days.

- (21) Appl. No.: **16/162,039**
- (22) Filed: **Oct. 16, 2018**

(65) **Prior Publication Data**
US 2019/0133588 A1 May 9, 2019

Related U.S. Application Data

- (60) Provisional application No. 62/581,059, filed on Nov. 3, 2017.

- (51) **Int. Cl.**
A61B 17/115 (2006.01)
A61B 17/11 (2006.01)
 (Continued)

- (52) **U.S. Cl.**
 CPC **A61B 17/1155** (2013.01); **A61B 17/1114** (2013.01); **A61F 5/445** (2013.01);
 (Continued)

- (58) **Field of Classification Search**
 CPC **A61B 17/1155**; **A61B 17/1114**; **A61B 17/07292**; **A61B 17/17257**;
 (Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

- 3,193,165 A 7/1965 Akhalaya et al.
 - 3,388,847 A 6/1968 Kasulin et al.
- (Continued)

FOREIGN PATENT DOCUMENTS

- CA 908529 A 8/1972
 - CA 2805365 A1 8/2013
- (Continued)

OTHER PUBLICATIONS

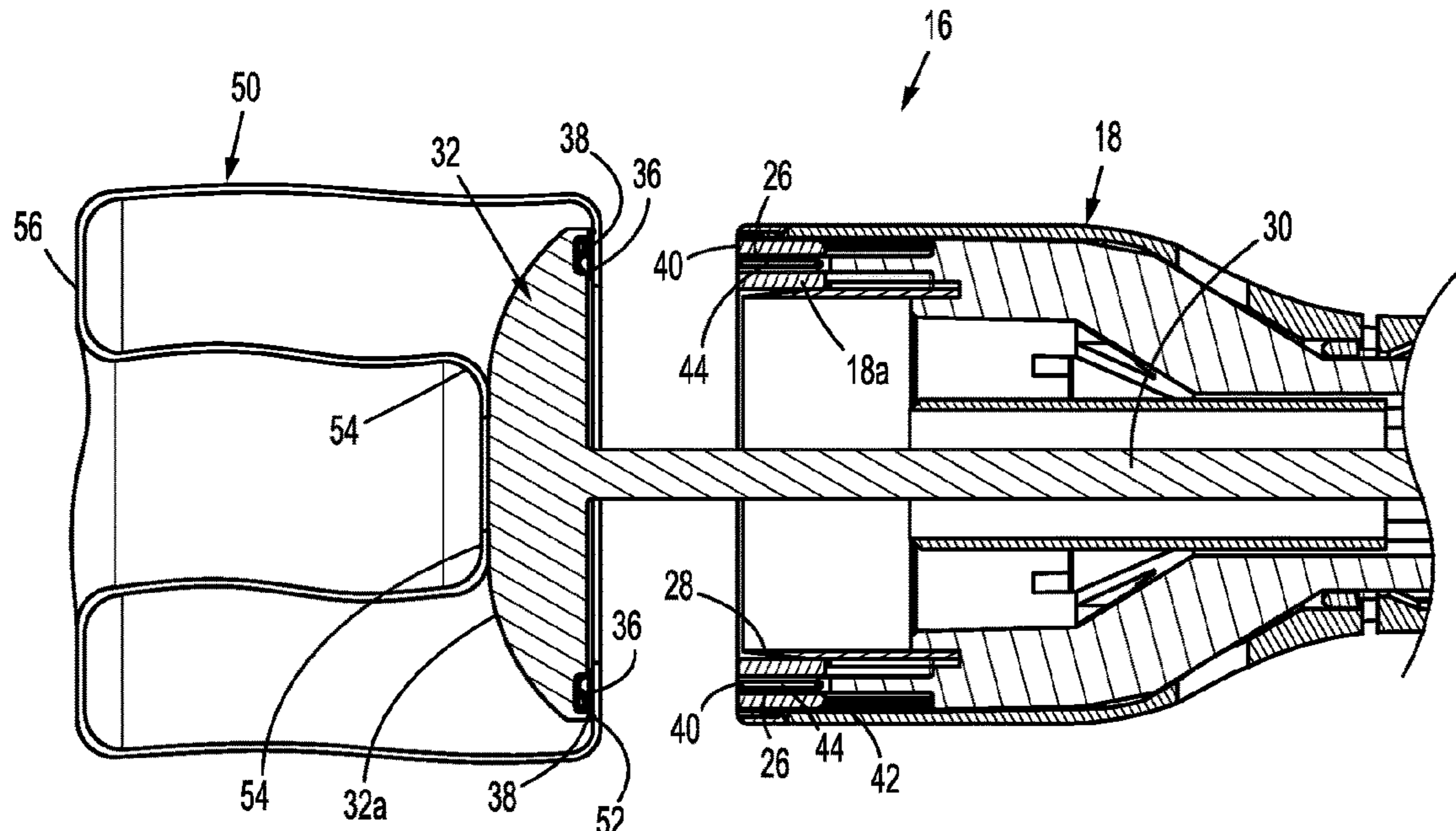
European Search Report dated Apr. 10, 2019, issued in EP Appln. No. 18204173.

Primary Examiner — Chelsea E Stinson
Assistant Examiner — Scott A Howell

(57) **ABSTRACT**

The presently disclosed stapling device includes a stomal sleeve secured to an anvil assembly of a tool assembly of the stapling device. The stomal sleeve has a tubular configuration having a first end portion secured to a tissue contact surface of the anvil assembly and a second end portion secured to a distal face of an anvil head of the anvil assembly. In use, the stapling device is fired to secure the first end portion of the stomal sleeve to dermal and intestinal tissue within a stoma and to separate the first end portion of the stomal sleeve from the anvil assembly. When the stapling device is withdrawn from the stoma, the second end portion of the stomal sleeve is withdrawn from the stoma and subsequently disengaged from the anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

7 Claims, 8 Drawing Sheets



(51)	Int. Cl.		5,197,649 A	3/1993	Bessler et al.
	<i>A61F 5/445</i>	(2006.01)	5,205,459 A	4/1993	Brinkerhoff et al.
	<i>A61B 17/072</i>	(2006.01)	5,221,036 A	6/1993	Takase
	<i>A61B 17/00</i>	(2006.01)	5,222,963 A	6/1993	Brinkerhoff et al.
(52)	U.S. Cl.		5,253,793 A	10/1993	Green et al.
	CPC	<i>A61B 17/07292</i> (2013.01); <i>A61B</i>	5,261,920 A	11/1993	Main et al.
		<i>2017/00004</i> (2013.01); <i>A61B 2017/07257</i>	5,271,543 A	12/1993	Grant et al.
		(2013.01); <i>A61B 2017/1132</i> (2013.01)	5,271,544 A	12/1993	Fox et al.
(58)	Field of Classification Search		5,275,322 A	1/1994	Brinkerhoff et al.
	CPC ..	<i>A61B 2017/17257</i> ; <i>A61B 2017/1132</i> ; <i>A61B</i>	5,282,810 A	2/1994	Allen et al.
		<i>2017/00336</i> ; <i>A61B 2017/3435</i> ; <i>A61B</i>	5,285,944 A	2/1994	Green et al.
		<i>5/4238</i> ; <i>A61B 5/6871</i> ; <i>A61B 2018/00494</i> ;	5,285,945 A	2/1994	Brinkerhoff et al.
		<i>A61B 1/00135</i> ; <i>A61B 2017/00004</i> ; <i>A61B</i>	5,292,053 A	3/1994	Bilotti et al.
		<i>2017/07257</i> ; <i>A61F 5/445</i>	5,309,927 A	5/1994	Welch
	See application file for complete search history.		5,312,024 A	5/1994	Grant et al.
(56)	References Cited		5,314,435 A	5/1994	Green et al.
	U.S. PATENT DOCUMENTS		5,314,436 A	5/1994	Wilk
			5,330,486 A	7/1994	Wilk
			5,333,773 A	8/1994	Main et al.
			5,344,059 A	9/1994	Green et al.
			5,346,115 A	9/1994	Perouse et al.
			5,348,259 A	9/1994	Blanco et al.
			5,350,104 A	9/1994	Main et al.
			5,355,897 A	10/1994	Pietrafitta et al.
			5,360,154 A	11/1994	Green
			5,368,215 A	11/1994	Green et al.
			5,392,979 A	2/1995	Green et al.
			5,395,030 A	3/1995	Kuramoto et al.
			5,403,333 A	4/1995	Kaster et al.
			5,404,870 A	4/1995	Brinkerhoff et al.
			5,411,508 A	5/1995	Bessler et al.
			5,425,738 A	6/1995	Gustafson et al.
			5,433,721 A	7/1995	Hooven et al.
			5,437,684 A	8/1995	Calabrese et al.
			5,439,156 A	8/1995	Grant et al.
			5,443,198 A	8/1995	Viola et al.
			5,447,514 A	9/1995	Gerry et al.
			5,454,825 A	10/1995	Van Leeuwen et al.
			5,464,415 A	11/1995	Chen
			5,470,006 A	11/1995	Rodak
			5,474,223 A	12/1995	Viola et al.
			5,497,934 A	3/1996	Brady et al.
			5,503,635 A	4/1996	Sauer et al.
			5,522,534 A	6/1996	Viola et al.
			5,533,661 A	7/1996	Main et al.
			5,588,579 A	12/1996	Schnut et al.
			5,609,285 A	3/1997	Grant et al.
			5,626,591 A	5/1997	Kockerling et al.
			5,632,433 A	5/1997	Grant et al.
			5,639,008 A	6/1997	Gallagher et al.
			5,641,111 A	6/1997	Ahrens et al.
			5,658,300 A	8/1997	Bito et al.
			5,669,918 A	9/1997	Balazs et al.
			5,685,474 A	11/1997	Seeber
			5,709,335 A	1/1998	Heck
			5,715,987 A	2/1998	Kelley et al.
			5,718,360 A	2/1998	Green et al.
			5,720,755 A	2/1998	Dakov
			5,732,872 A	3/1998	Bolduc et al.
			5,749,896 A	5/1998	Cook
			5,758,814 A	6/1998	Gallagher et al.
			5,799,857 A	9/1998	Robertson et al.
			5,814,055 A	9/1998	Knodel et al.
			5,833,698 A	11/1998	Hinchliffe et al.
			5,836,503 A	11/1998	Ehrenfels et al.
			5,839,639 A	11/1998	Sauer et al.
			5,855,312 A	1/1999	Toledano
			5,860,581 A	1/1999	Robertson et al.
			5,868,760 A	2/1999	McGuckin, Jr.
			5,881,943 A	3/1999	Heck et al.
			5,915,616 A	6/1999	Viola et al.
			5,947,363 A	9/1999	Bolduc et al.
			5,951,576 A	9/1999	Wakabayashi
			5,957,363 A	9/1999	Heck
			5,993,468 A	11/1999	Rygaard
			6,024,748 A	2/2000	Manzo et al.
			6,050,472 A	4/2000	Shibata
			6,053,390 A	4/2000	Green et al.
			6,068,636 A	5/2000	Chen

(56)

References Cited

U.S. PATENT DOCUMENTS

2008/0135044 A1* 6/2008 Freitag A61M 16/16
128/200.26

2009/0236392 A1 9/2009 Cole et al.
2009/0236398 A1 9/2009 Cole et al.
2009/0236401 A1 9/2009 Cole et al.
2010/0019016 A1 1/2010 Edoga et al.
2010/0051668 A1 3/2010 Milliman et al.
2010/0084453 A1 4/2010 Hu
2010/0147923 A1 6/2010 D'Agostino et al.
2010/0163598 A1 7/2010 Belzer
2010/0224668 A1 9/2010 Fontayne et al.
2010/0230465 A1 9/2010 Smith et al.
2010/0258611 A1 10/2010 Smith et al.
2010/0264195 A1 10/2010 Bettuchi
2010/0327041 A1 12/2010 Milliman et al.
2011/0011916 A1 1/2011 Levine
2011/0114697 A1 5/2011 Baxter, III et al.
2011/0114700 A1 5/2011 Baxter, III et al.
2011/0144640 A1 6/2011 Heinrich et al.
2011/0147432 A1 6/2011 Heinrich et al.
2011/0192882 A1 8/2011 Hess et al.
2011/0278346 A1 11/2011 Hull et al.
2012/0145755 A1 6/2012 Kahn
2012/0193395 A1 8/2012 Pastorelli et al.
2012/0193398 A1 8/2012 Williams et al.
2012/0232339 A1 9/2012 Csiky
2012/0253329 A1 10/2012 Zemlok et al.
2012/0273548 A1 11/2012 Ma et al.
2012/0325888 A1 12/2012 Qiao et al.
2013/0015232 A1 1/2013 Smith et al.
2013/0020372 A1 1/2013 Jankowski et al.
2013/0020373 A1 1/2013 Smith et al.
2013/0032628 A1 2/2013 Li et al.
2013/0056516 A1 3/2013 Viola
2013/0060258 A1 3/2013 Giacomantonio
2013/0105544 A1 5/2013 Mozdzierz et al.
2013/0105546 A1 5/2013 Milliman et al.
2013/0105551 A1 5/2013 Zingman
2013/0126580 A1 5/2013 Smith et al.
2013/0153630 A1 6/2013 Miller et al.
2013/0153631 A1 6/2013 Vasudevan et al.
2013/0153633 A1 6/2013 Casasanta, Jr. et al.
2013/0153634 A1 6/2013 Carter et al.
2013/0153635 A1* 6/2013 Hodgkinson A61B 17/07207
227/176.1

2013/0153638 A1 6/2013 Carter et al.
2013/0153639 A1 6/2013 Hodgkinson et al.
2013/0175315 A1 7/2013 Milliman
2013/0175318 A1 7/2013 Felder et al.
2013/0175319 A1 7/2013 Felder et al.
2013/0175320 A1 7/2013 Mandakolathur Vasudevan et al.
2013/0181035 A1 7/2013 Milliman
2013/0181036 A1* 7/2013 Olson A61B 17/068
227/180.1

2013/0186930 A1 7/2013 Wenchell et al.
2013/0193185 A1 8/2013 Patel
2013/0193187 A1 8/2013 Milliman
2013/0193190 A1 8/2013 Carter et al.
2013/0193191 A1 8/2013 Stevenson et al.
2013/0193192 A1 8/2013 Casasanta, Jr. et al.
2013/0200131 A1 8/2013 Racenet et al.
2013/0206816 A1 8/2013 Penna

2013/0214027 A1* 8/2013 Hessler A61B 17/115
227/175.1

2013/0214028 A1 8/2013 Patel et al.
2013/0228609 A1 9/2013 Kostrzewski
2013/0240597 A1 9/2013 Milliman et al.
2013/0240600 A1 9/2013 Bettuchi
2013/0248581 A1 9/2013 Smith et al.
2013/0277411 A1 10/2013 Hodgkinson et al.
2013/0277412 A1 10/2013 Gresham et al.
2013/0284792 A1 10/2013 Ma
2013/0292449 A1 11/2013 Bettuchi et al.
2013/0299553 A1 11/2013 Mozdzierz
2013/0299554 A1 11/2013 Mozdzierz
2013/0306701 A1 11/2013 Olson
2013/0306707 A1 11/2013 Viola et al.
2014/0008413 A1 1/2014 Williams
2014/0012317 A1 1/2014 Orban et al.
2014/0097224 A1* 4/2014 Prior A61B 17/105
227/176.1

2014/0209658 A1* 7/2014 Skalla A61B 17/1155
227/175.1

2014/0222039 A1* 8/2014 Khosrovaninejad A61F 2/04
606/151

2016/0143641 A1 5/2016 Sapienza et al.
2016/0157856 A1 6/2016 Williams et al.
2016/0174988 A1 6/2016 D'Agostino et al.
2016/0302792 A1 10/2016 Motai
2018/0078260 A1* 3/2018 Matonick A61B 17/1114

FOREIGN PATENT DOCUMENTS

DE 1057729 B 5/1959
DE 3301713 A1 7/1984
EP 0152382 A2 8/1985
EP 0173451 A1 3/1986
EP 0190022 A2 8/1986
EP 0282157 A1 9/1988
EP 0503689 A2 9/1992
EP 1354560 A2 10/2003
EP 1588667 A1 10/2005
EP 2138118 A2 12/2009
EP 2168510 A1 3/2010
EP 2238926 A2 10/2010
EP 2524656 A2 11/2012
FR 1136020 A 5/1957
FR 1461464 A 2/1966
FR 1588250 A 4/1970
FR 2443239 A1 7/1980
GB 1185292 A 3/1970
GB 2016991 A 9/1979
GB 2070499 A 9/1981
JP 2004147969 A 5/2004
JP 2013138860 A 7/2013
NL 7711347 A 4/1979
SU 1509052 A1 9/1989
WO 8706448 A1 11/1987
WO 8900406 A1 1/1989
WO 9006085 A1 6/1990
WO 98/35614 A1 8/1998
WO 0154594 A1 8/2001
WO 2008107918 A1 9/2008
WO 2018057324 A1 3/2018
WO 2018140066 A1 8/2018

* cited by examiner

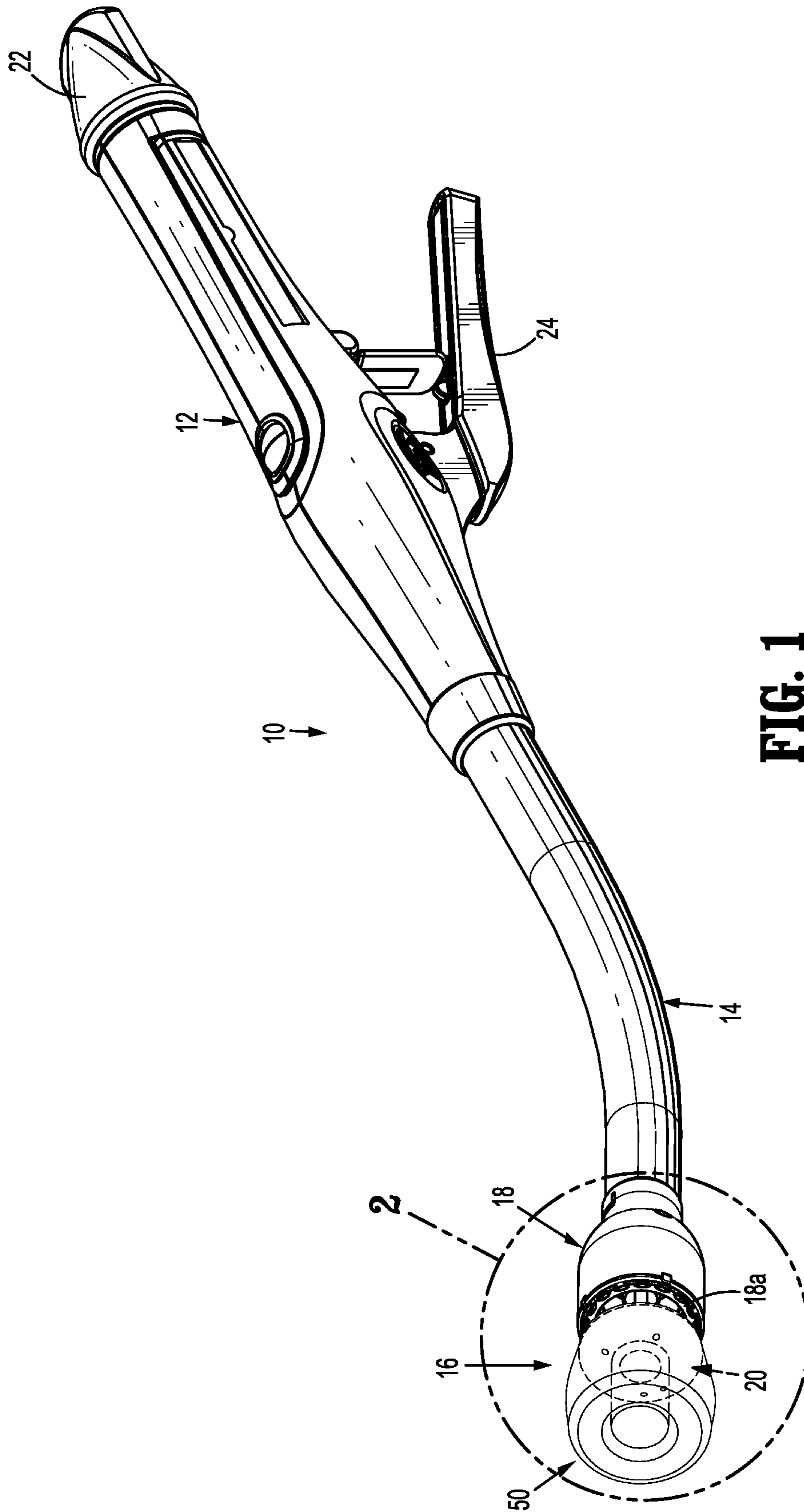


FIG. 1

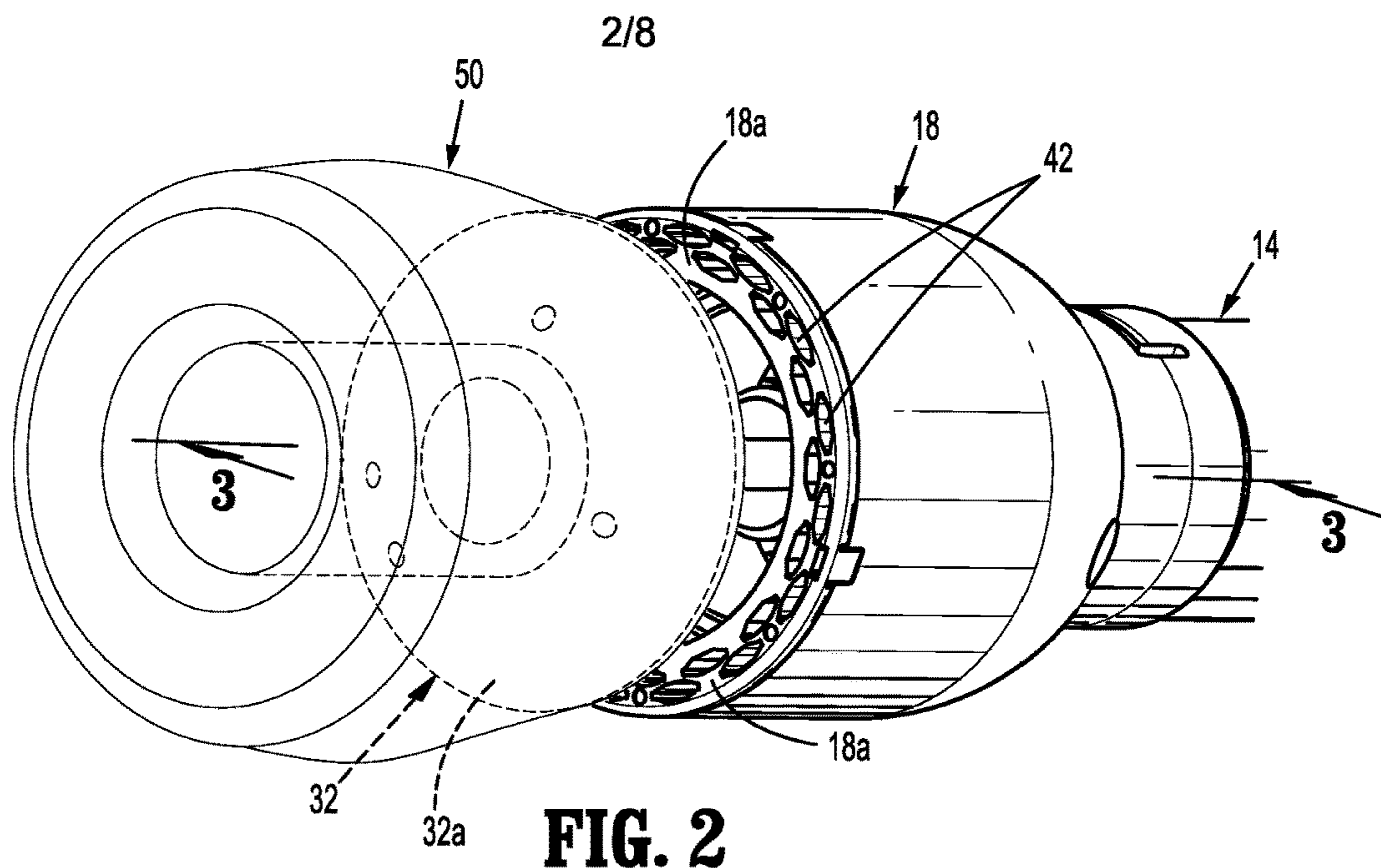


FIG. 2

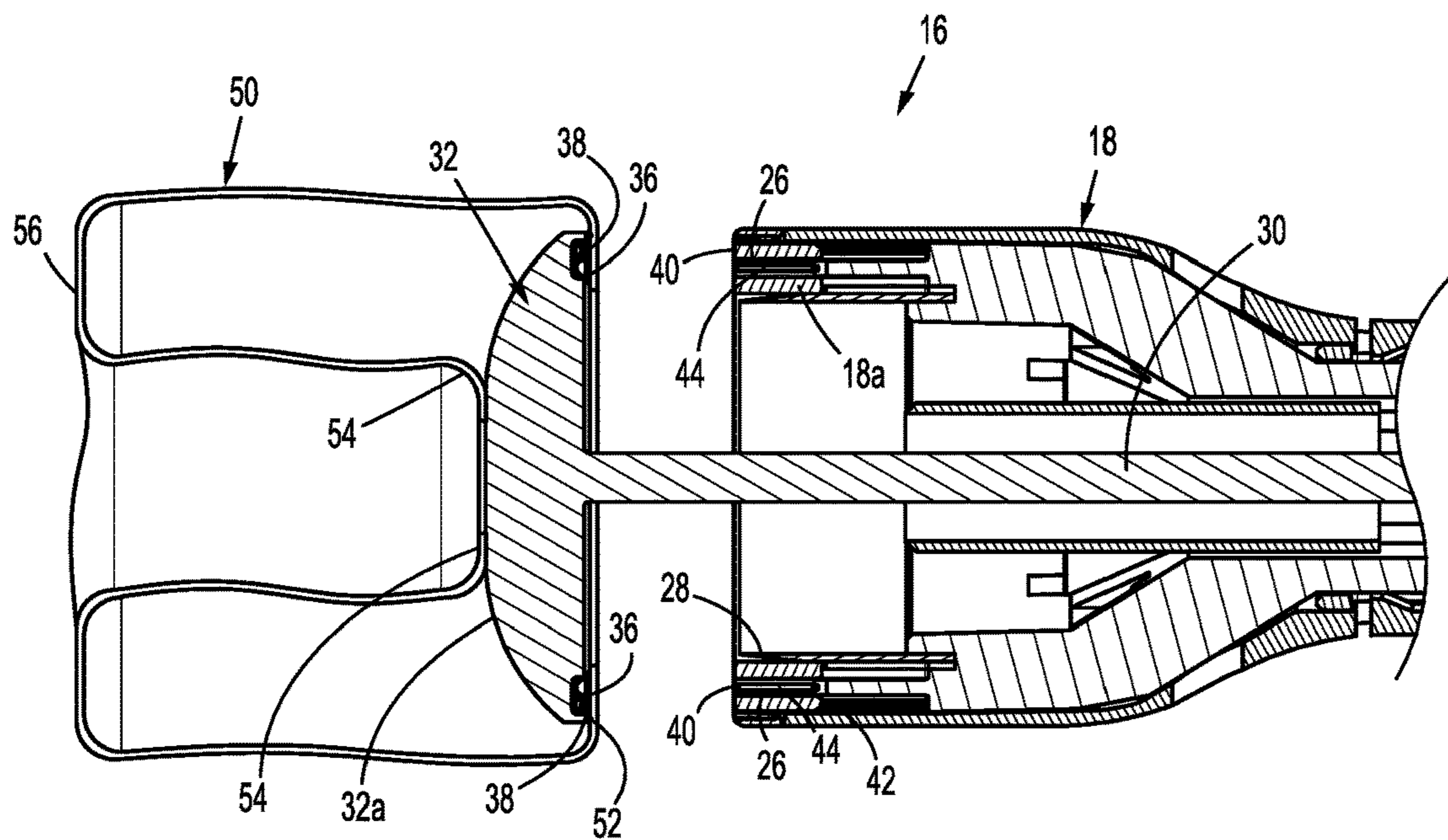


FIG. 3

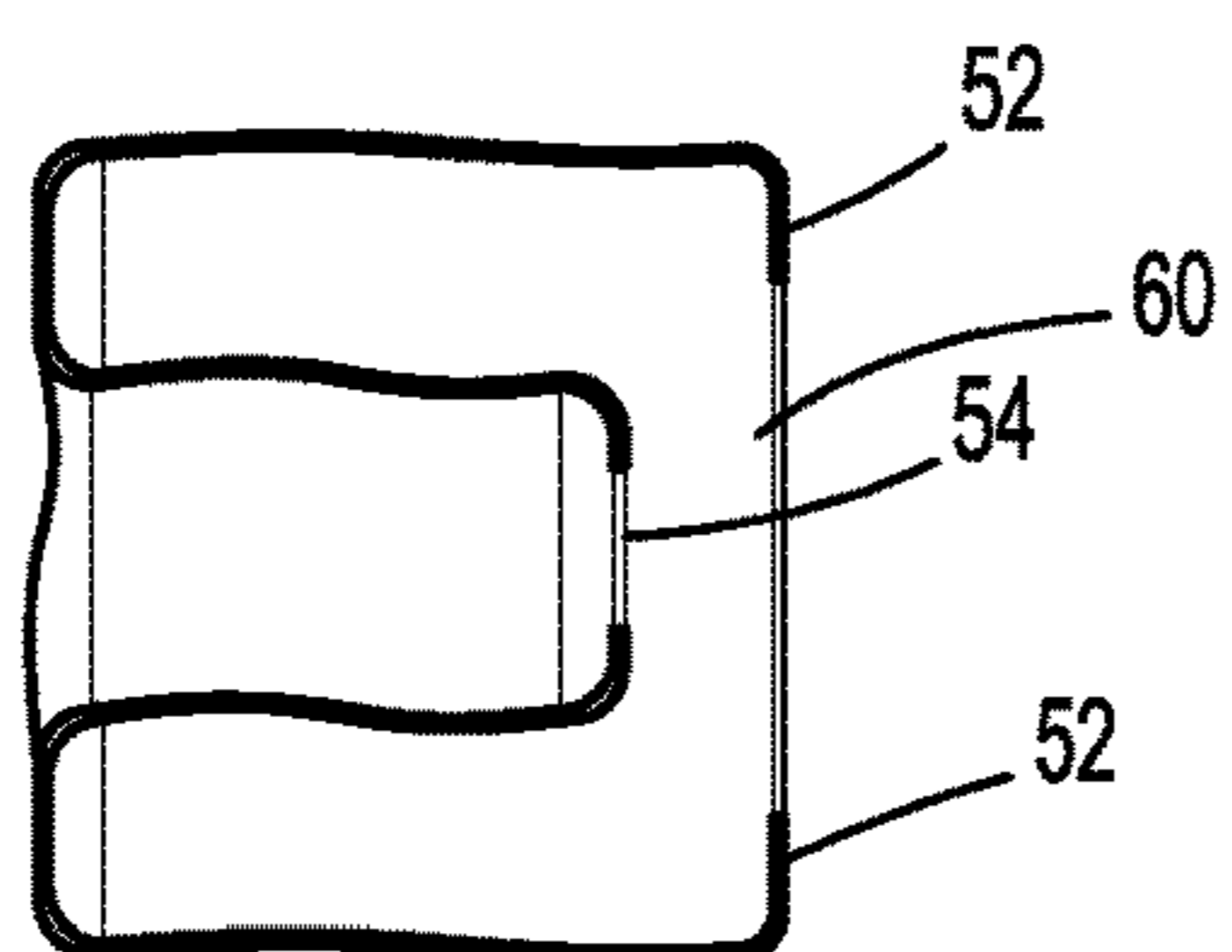


FIG. 3A

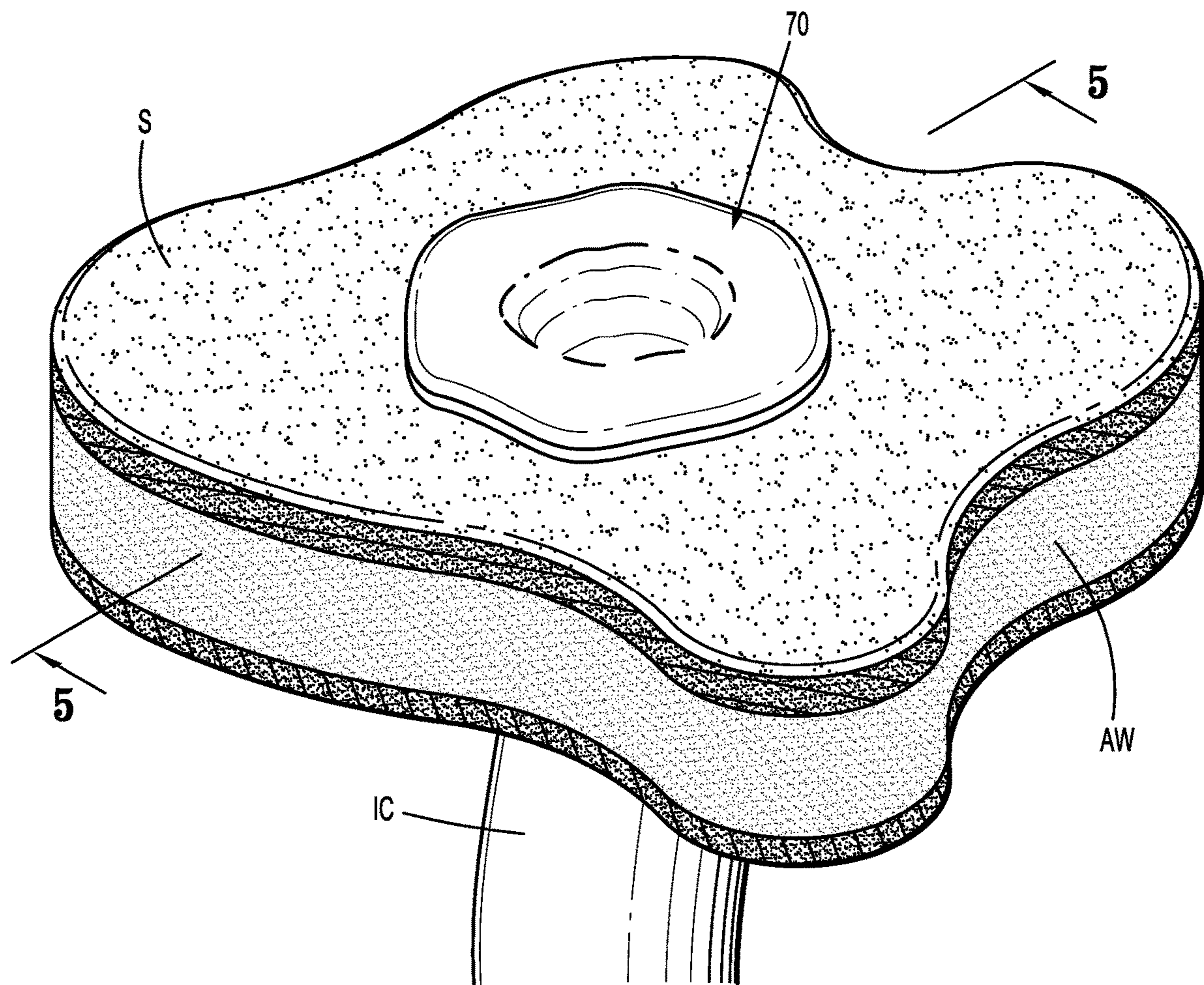


FIG. 4

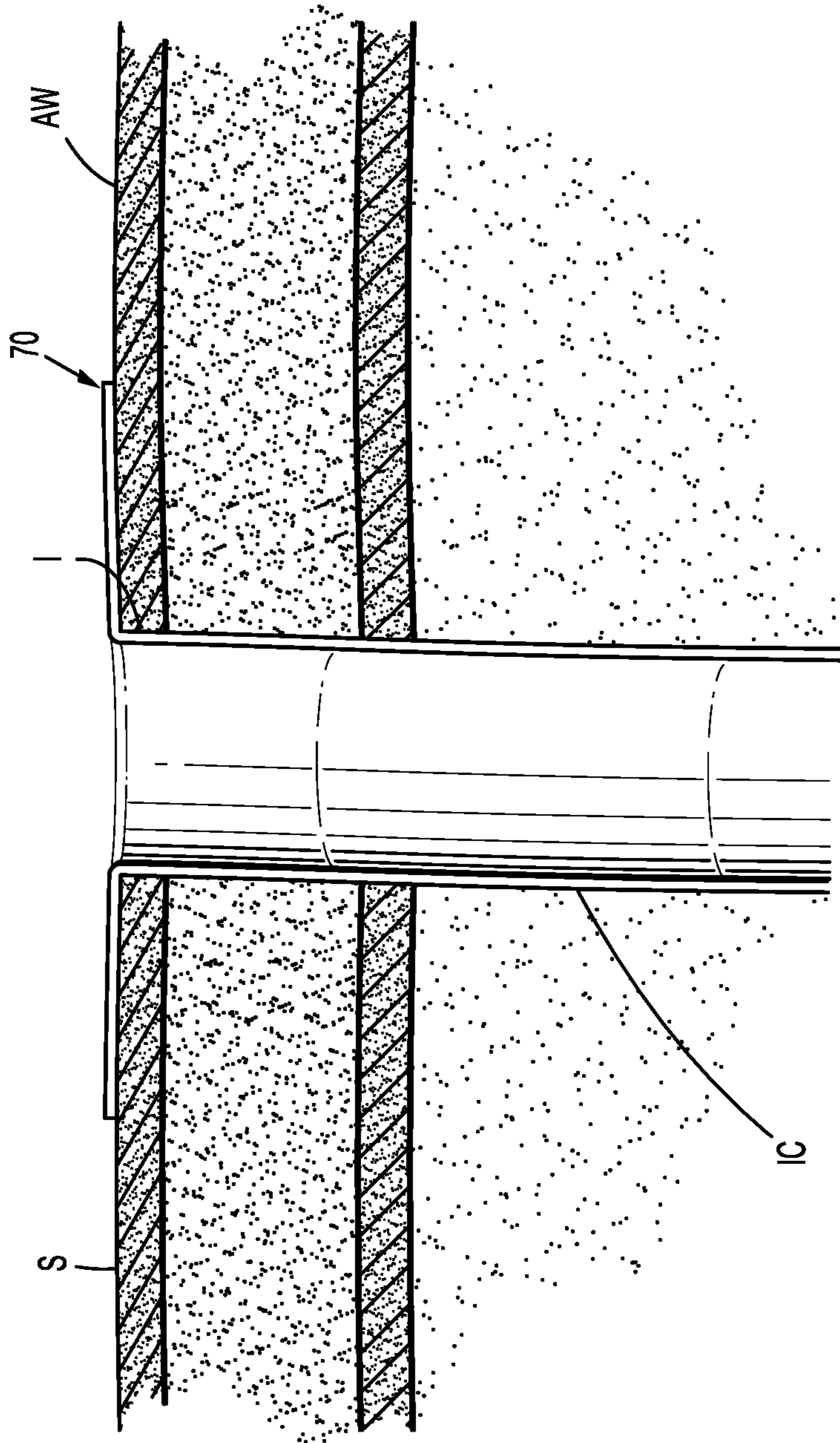


FIG. 5

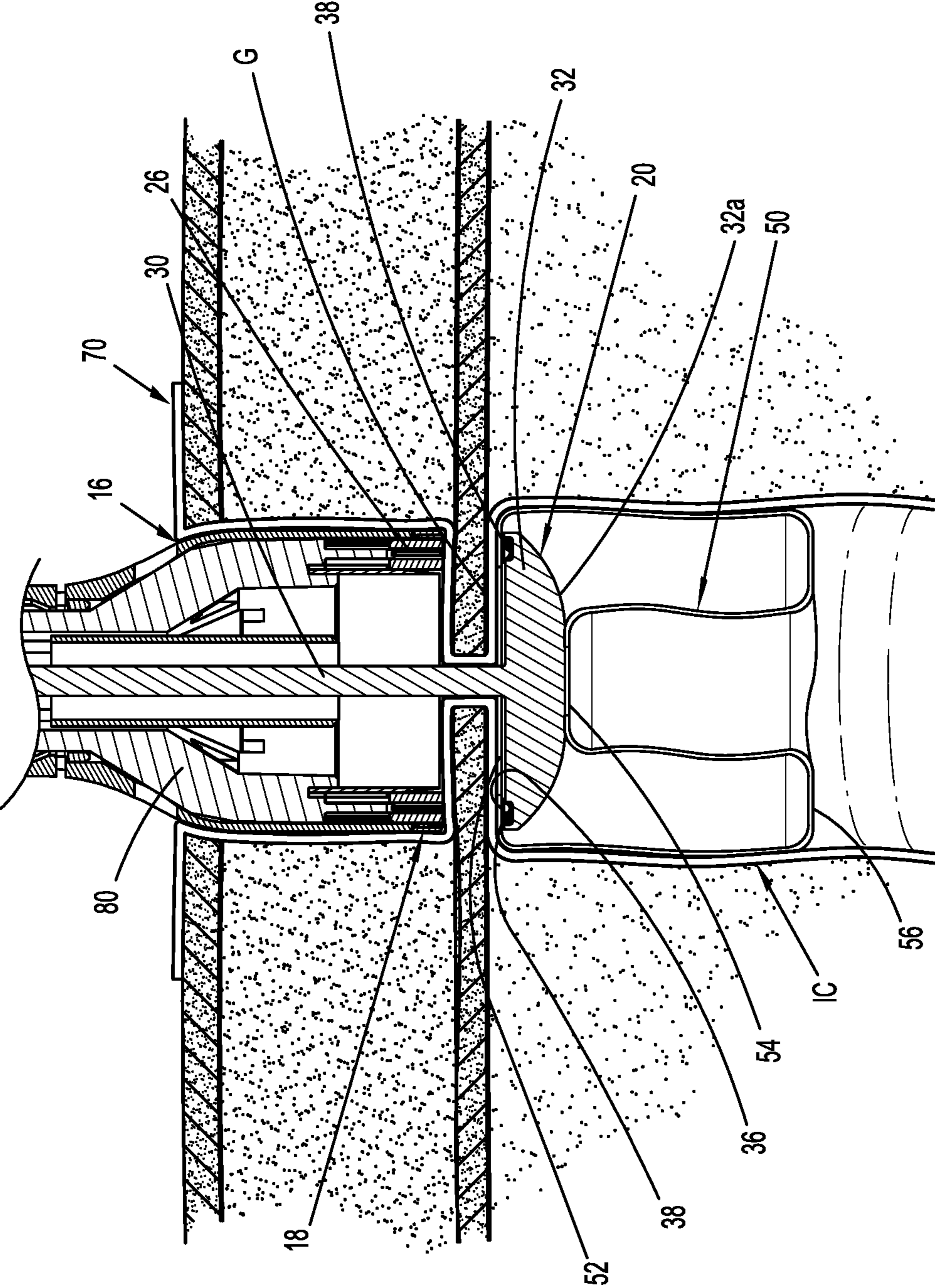


FIG. 6

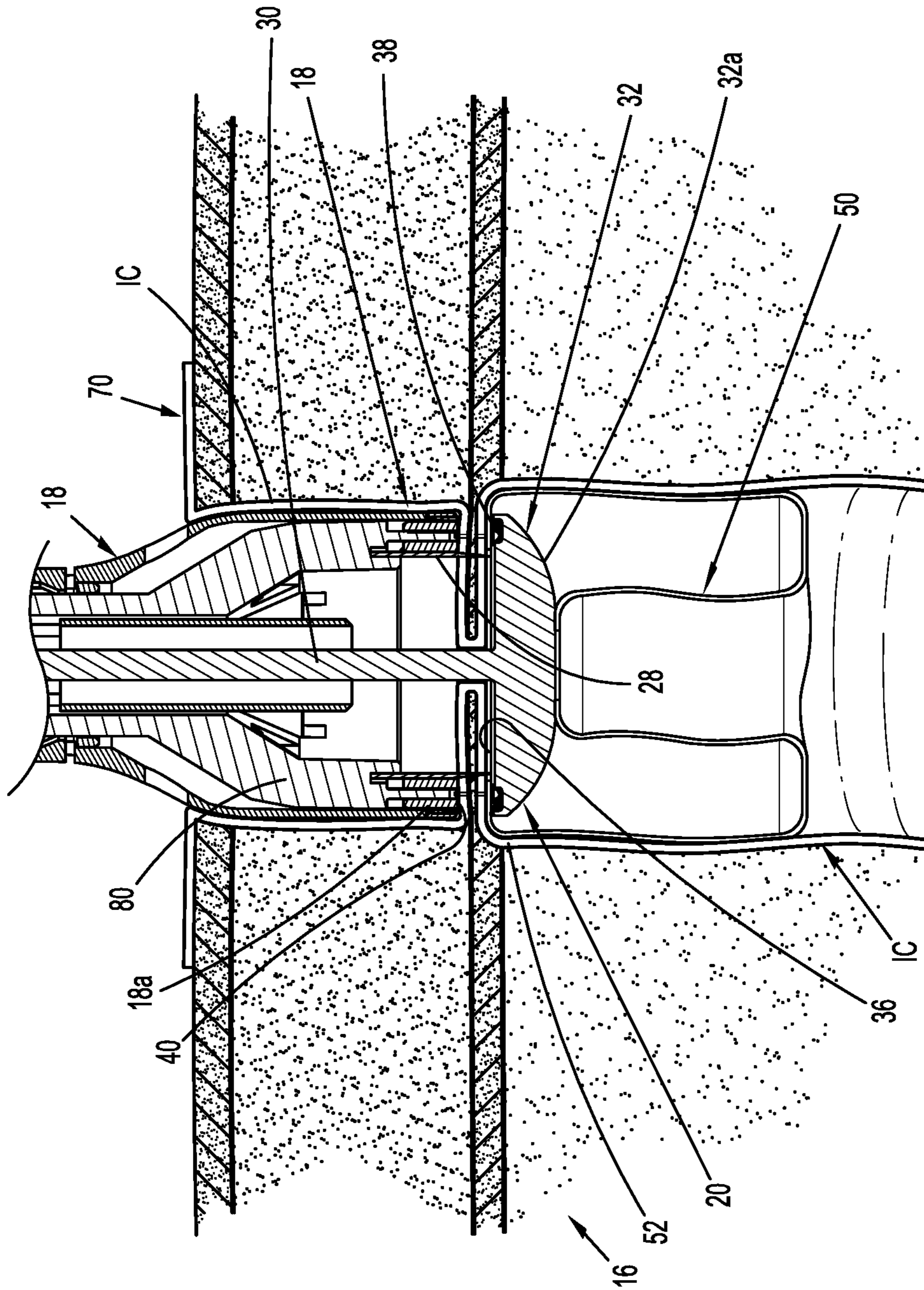


FIG. 7

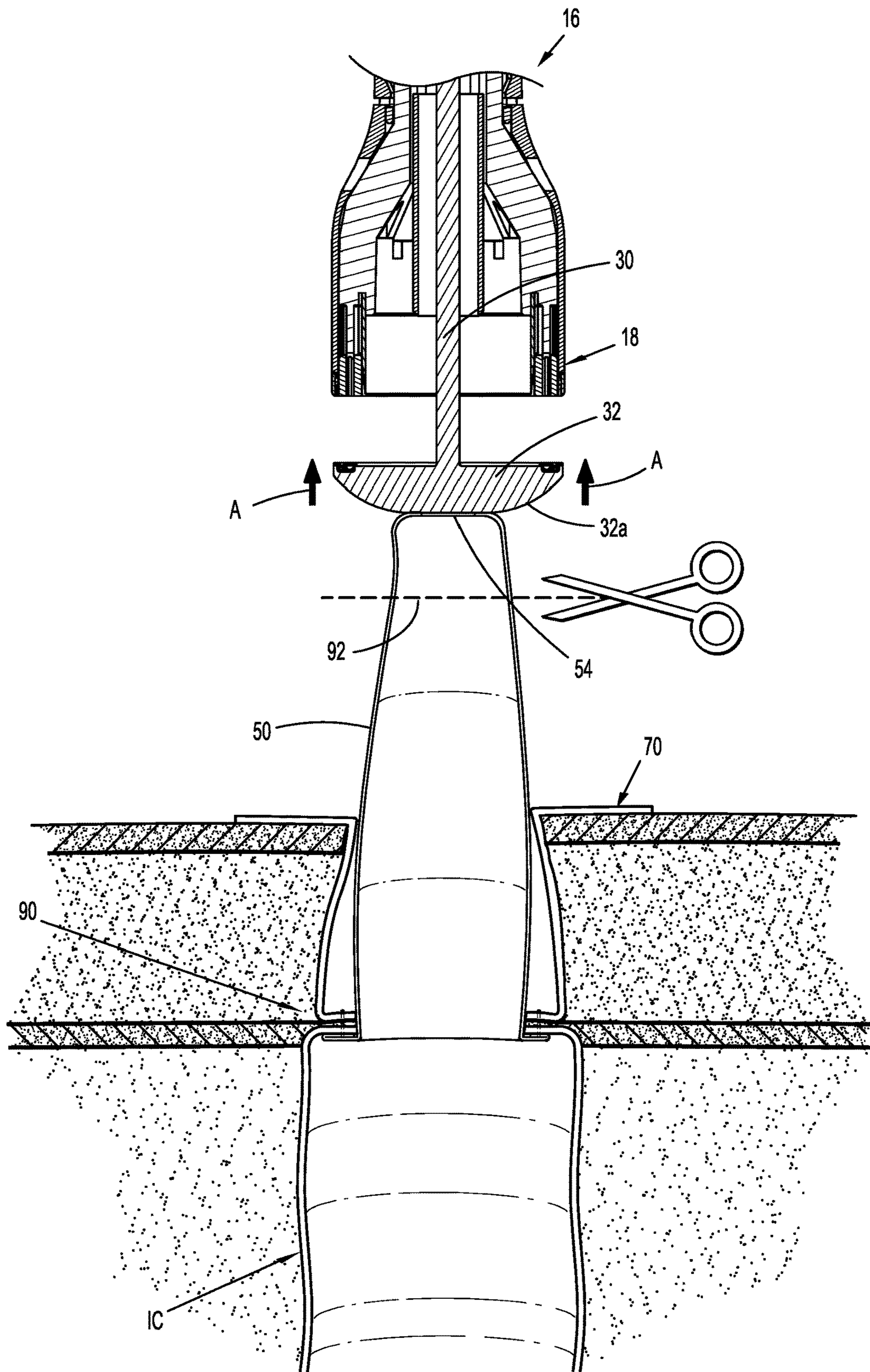


FIG. 8

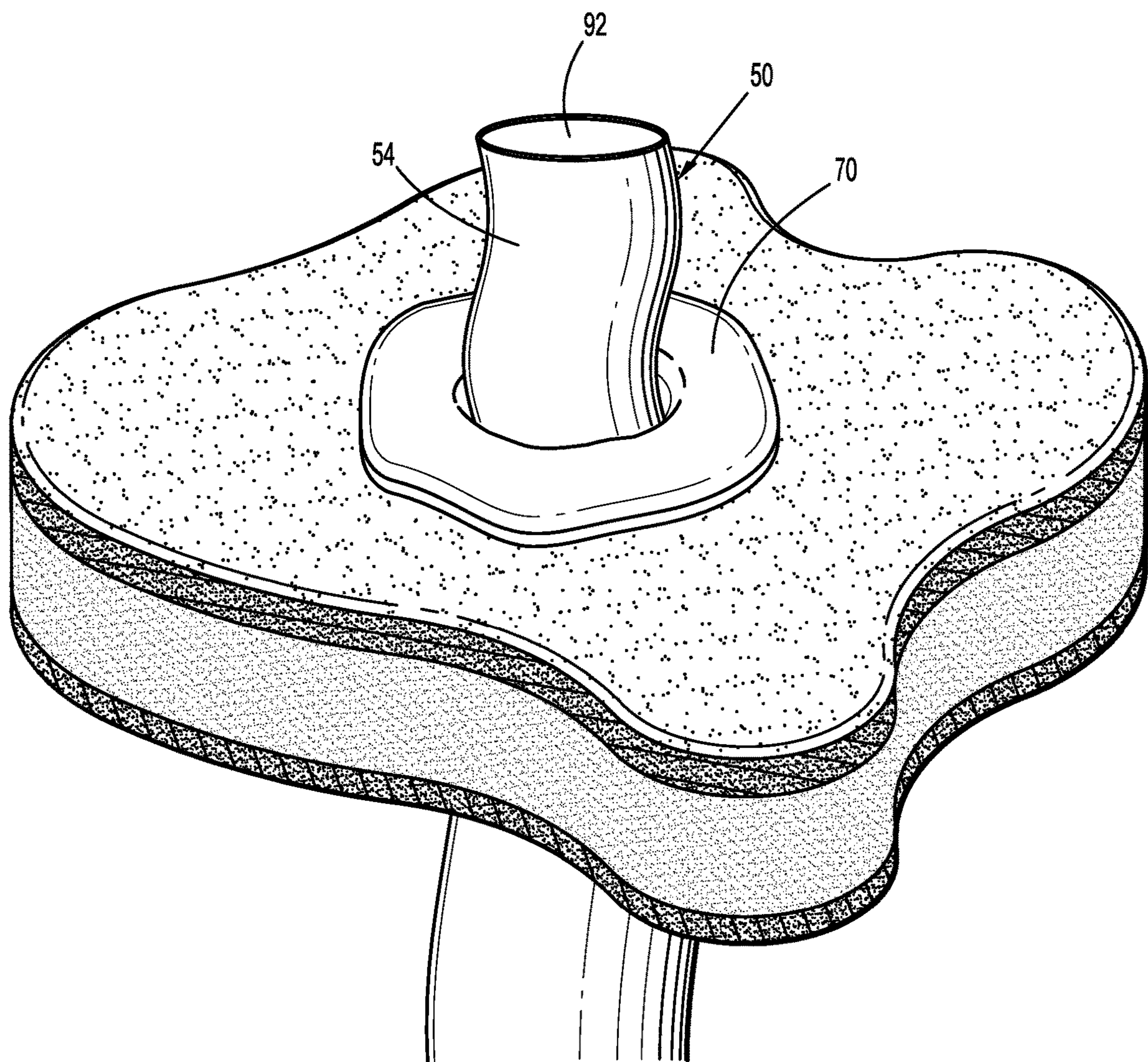


FIG. 9

1**DEVICE AND METHOD FOR ATTACHMENT
OF A STOMAL SLEEVE****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application claims the benefit of and priority to U.S. Provisional Patent Application Ser. No. 62/581,059 filed Nov. 3, 2017, the entire disclosure of which is incorporated by reference herein.

BACKGROUND**1. Technical Description**

The present disclosure is directed to a device and method for attaching a stomal sleeve to a stoma and, more particularly, to method of attaching a stomal sleeve to a stoma using a circular stapling device.

2. Background of Related Art

During an ostomy procedure, a bisected portion of an intestine is secured to an exterior surface of the abdominal wall to provide internal access into the intestine for collecting fecal matter. The exteriorization of the intestine is called a stoma. Ostomy procedures include ileostomies and colostomies. In an ileostomy procedure, an end of the ileum (i.e., small intestine) is pulled through the abdominal wall and is flared outwardly and sutured to the skin, leaving a smooth, rounded, inside-out ileum as the stoma. In a colostomy procedure, an end or portion of the colon is pulled through the abdominal wall and flared outwardly and fastened (e.g., stitched) to the skin of the patient to form a stoma.

Ostomy surgery is sometimes performed on an emergency basis due to diverticulitis, trauma, radiation complications, volvulus, necrotic bowel, bowel perforation, etc. Children and adults alike may require an ostomy. An ostomy may only be temporary to allow for healing of the bowel or a decrease of inflammation at the surgical site. In some instances an ostomy may be permanent.

Typically, an ostomy bag is secured to the stoma to collect fecal matter from the intestine. If the fecal matter leaks and/or contacts the skin of a patient defining the stoma, the patient's skin can become irritated and/or infected causing the patient pain and discomfort. As such, a need exists for a surgical instrument and method for bypassing an area adjacent the stoma to minimize contact between the patient's skin and fecal matter being collected in the ostomy bag.

SUMMARY

In one aspect of the present disclosure, a stapling device includes a tool assembly having an anvil assembly and a shell assembly. The anvil assembly has an anvil shaft and an anvil head having an annular configuration supported on the anvil shaft. The anvil head defines a first tissue contact surface and includes an annular array of staple deforming pockets positioned about the first tissue contacting surface. The shell assembly has a staple cartridge including a second tissue contact surface having an annular array of staple receiving pockets. The tool assembly is movable from an unapproximated position in which the anvil assembly is spaced from the staple cartridge to an approximated position in which the tissue contacting surfaces of the anvil assembly and the staple cartridge are in closer juxtaposed alignment. A stomal sleeve has a tubular configuration, a first end

2

portion secured to the first tissue contacting surface of the anvil head radially inwardly of the annular array of staple deforming pockets, and a second end portion secured to a distal surface of the anvil head.

5 In embodiments, the cartridge assembly includes an annular knife that is movable from a retracted position recessed within the staple cartridge to an advanced position in contact with the anvil head.

10 In some embodiments, in the advanced position of the annular knife, the annular knife is positioned to engage the first end portion of the stomal sleeve.

In certain embodiments, the second end portion of the stomal sleeve is closed.

15 In embodiments, the first end portion of the stomal sleeve defines an opening.

In some embodiments, the stomal sleeve is formed from a non-degradable, bio-compatible, pliable material.

In certain embodiments, the stomal sleeve is formed from a polymeric material.

20 In embodiments, the first and second end portions of the stomal sleeve are secured to the anvil head using an adhesive.

In another aspect of the disclosure, a method of attaching a stomal sleeve to a stoma using a circular stapling device includes inserting a tool assembly of the circular stapling device into the stoma with a stomal sleeve attached to an anvil assembly of the tool assembly, wherein the stomal sleeve has a first end portion connected to a first tissue contact surface of the anvil assembly and a second end portion attached to a distal face of an anvil head of the anvil assembly; positioning dermal and intestinal tissue into a tissue gap defined between a staple cartridge of a shell assembly of the tool assembly and the anvil assembly; approximating the shell assembly of the tool assembly with the anvil assembly to clamp the dermal and intestinal tissue between the shell and anvil assemblies; firing the circular stapling device to secure the first end portion of the stomal sleeve to the dermal and intestinal tissue; withdrawing the circular stapling device from the stoma to withdraw a second end portion of the stomal sleeve from the stoma; and disengaging the second end portion of the stomal sleeve from the anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

45 In embodiments, the method includes detaching the stomal sleeve from the tissue contact surface of the anvil assembly.

In embodiments, detaching the stomal sleeve from the tissue contact surface of the anvil is effected by an annular knife of the shell assembly.

50 In embodiments, the method includes cutting the second end portion of the stomal sleeve to separate the second end portion of the stomal sleeve from the anvil assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

55 Various embodiments of the presently disclosed stapling device and method for attaching a stomal sleeve to a stoma are described herein below with reference to the drawings, wherein:

60 FIG. 1 is a side perspective view of one embodiment of the presently disclosed surgical stapling device supporting a stomal sleeve on an anvil assembly of the stapling device;

FIG. 2 is an enlarged view of the indicated area of detail shown in FIG. 1;

65 FIG. 3 is a side cross-sectional view taken along section line 3-3 of FIG. 2;

3

FIG. 3A is a side view of the stomal sleeve of the surgical stapling device of FIG. 1;

FIG. 4 is a side perspective view of a stoma of a bowel extending through an opening in an abdomen of a patient;

FIG. 5 is a cross-sectional view taken along section line 5-5 of FIG. 4;

FIG. 6 is a side cross-sectional view of the surgical stapling device of FIG. 1 inserted into the stoma of FIG. 5 prior to full approximation of the stapling device with the stomal sleeve extending from the anvil assembly into the intestine/colon of the patient;

FIG. 7 is side cross-sectional view of the surgical stapling device of FIG. 1 inserted into the stoma of FIG. 5 with the stapling device in an approximated and fired condition and the stomal sleeve extending from the anvil assembly into the intestine/colon of the patient;

FIG. 8 is side cross-sectional view of the surgical stapling device of FIG. 1 as the stapling device is withdrawn from the stoma of FIG. 7 after the stapling device is fired with the stomal sleeve attached to the anvil assembly and extending from the stoma of the patient; and

FIG. 9 is a side perspective view of the stomal sleeve extending from the stoma of the patient after the stomal sleeve is cut and separated from the anvil assembly;

DETAILED DESCRIPTION OF EMBODIMENTS

The presently disclosed device and method for attaching a stomal sleeve to a stoma will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. In this description, the term “proximal” is used generally to refer to that portion of the device that is closer to a clinician, while the term “distal” is used generally to refer to that portion of the device that is farther from the clinician. In addition, the term clinician is used generally to refer to medical personnel including surgeons, doctors, nurses, and support personnel.

The presently disclosed stapling device has a stomal sleeve secured to an anvil assembly of the stapling device. The stapling device includes a tool assembly having an annular cartridge, an annular anvil assembly that is movable in relation to the annular cartridge between unapproximated and approximated positions, and an annular knife that is moveable into the anvil assembly to cut tissue and disengage one end of the stomal sleeve from attachment with the anvil assembly when the stapling device is fired. The anvil assembly includes an anvil head that defines a tissue contact surface. The stomal sleeve has a tubular configuration having a first end portion secured to the tissue contact surface of the anvil head and a second end portion secured to a distal face of the anvil head.

The presently disclosed method of attaching a stomal sleeve to a stoma includes inserting the tool assembly of the stapling device into the stoma with the stomal sleeve attached to the anvil assembly; positioning dermal and intestinal tissue into a tissue gap defined between the cartridge and anvil assemblies; approximating the cartridge and anvil assemblies to clamp the dermal and intestinal tissue between the cartridge and anvil assemblies; firing the stapling device to secure the first end portion of the stomal sleeve to the dermal and intestinal tissue; withdrawing the stapling device from the stoma to withdraw the second end portion of the stomal sleeve from the stoma; and disengaging the second end portion of the stomal sleeve from the

4

anvil head of the anvil assembly such that the second end portion of the stomal sleeve is positioned externally of the stoma.

Particular embodiments of the present disclosure are described below with reference to the accompanying drawings. However, it is to be understood that the disclosed embodiments are merely examples of the disclosure and may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to employ the present disclosure in virtually any appropriately detailed structure.

Referring to FIG. 1, the presently disclosed device for attaching a stomal sleeve to a stoma is identified in the figures generally as 10 and includes a handle assembly 12, an elongated body portion 14, and a tool assembly 16. The tool assembly 16 includes an annular shell assembly 18 having an annular staple cartridge 18a and an annular anvil assembly 20 that are movable in relation to each other between an unapproximated or spaced position and an approximated position. The handle assembly 12 includes an approximation knob 22 that is actuatable to move the anvil assembly 20 in relation to the cartridge assembly 18 between the spaced and approximated positions to clamp tissue and a firing trigger 24 that is actuatable to fire staples 26 (FIG. 3) from the staple cartridge 18a into tissue and to advance an annular knife 28 (FIG. 3) into the anvil assembly 20. For a detailed description of an exemplary stapling device suitable for use for attaching a stomal sleeve to a stoma, see U.S. Pat. No. 7,857,187 (“the ’187 patent”) which is incorporated herein by reference in its entirety.

Although the presently disclosed stapling device 10 is shown and described as being a manually powered device, it is envisioned that the stapling device 10 can be an electrically powered device such as described in U.S. Patent Publication No. 2012/0253329 which is incorporated herein by reference in its entirety.

Referring to FIGS. 2 and 3, the anvil assembly 20 includes an anvil shaft 30 (FIG. 3) and an anvil head 32 secured to a distal portion of the anvil shaft 30. The anvil head 32 has a distally facing surface 32a and is attached to a distal portion of the anvil shaft 30 as shown in FIG. 3. Alternatively, the anvil head 32 can be pivotally attached to the distal portion of the anvil shaft 30 such as described in the ’187 patent. A proximal end of the anvil shaft 30 is connected to an approximation mechanism of the device 10. The anvil shaft 30 can be fixedly connected to the approximation mechanism of the device 10 as shown, or, in the alternative, the anvil shaft 30 can be removably connected to the approximation mechanism of the device 10, as described in the ’187 patent. For a more detailed description of the interconnection between the anvil shaft and the approximation mechanism of the device 10, see the ’187 patent.

The anvil head 32 defines a first annular tissue contact surface 36 that includes a plurality of staple deforming pockets 38. The staple deforming pockets 38 (FIG. 3) are disposed in an annular array about the first annular tissue contact surface 36. The staple cartridge 18a includes a second annular tissue contact surface 40 and includes a plurality of staple pockets 42. The staple pockets 42 are positioned in an annular array about the second tissue contact surface 40 and receive staples 44. The cartridge assembly 18 also includes the annular knife 28 that is positioned to engage the anvil head 32 within the annular

5

array of staple deforming pockets **38** when the stapling device is fired as discussed in further detail below. For a more detailed description of the cartridge and anvil assemblies, see the '187 patent.

The anvil head **32** supports a stomal sleeve **50** that has a tubular configuration and may be formed from a biocompatible, non-degradable, pliable material, e.g., a polymeric material. In embodiments, the stomal sleeve **50** has a first end portion **52** that is secured to the first tissue contact surface **36** of the anvil head **32** at a location radially inwardly of the annular array of staple deforming pockets **38** and a second end portion **54** that is secured to the distally facing surface **32a** of the anvil head **32** such that a central portion **56** of the stomal sleeve **50** is positioned distally of the second end portion **54** of the stomal sleeve **50**. The end portions **52**, **54** of the stomal sleeve can be secured to the anvil head **32** using adhesives or the like. In embodiments, the first end portion **52** of the stomal sleeve **50** defines an opening **60** (FIG. 3A) and the second end portion **54** is closed. It is envisioned that both of the first and second end portions **52**, **54** of the stomal sleeve **50** can initially define an opening or be closed.

Referring to FIGS. 4 and 5, during formation of a stoma **70**, a vessel portion, e.g., small or large intestine or colon "IC", is pulled through an incision "I" (FIG. 5) in the abdominal wall "AW" and is everted outwardly and secured to an outer surface of the skin "S", leaving a smooth, rounded, everted vessel portion as the stoma **70**. An ostomy bag (not shown) is secured to the stoma **70** to direct fecal matter from within the vessel portion "IC" into the ostomy bag. Formation of the stoma can be performed using a variety of techniques and devices and does not form part of the presently disclosed method. Embodiments of a stapling device and method for forming a stoma are described in U.S. application Ser. No. [203-11280] which is incorporated herein in its entirety by reference.

Referring to FIG. 6, after the stoma **70** is created, in order to attach the stomal sleeve **50** to a position within the vessel portion "IC", the tool assembly **16** of the stapling device **10** is inserted through the stoma **70** with the cartridge assembly **18** and anvil assembly **20** in an unapproximated position. In this position, the stomal sleeve **50** is supported on the anvil head **32** and extends into the vessel portion "IC" distally of the anvil head **32**. With the tool assembly **16** positioned within the vessel portion "IC", tissue including a portion of the vessel portion "IC" is drawn into the tissue into tissue gap "G" defined between the staple cartridge **18a** and the anvil assembly **20**. As discussed above, the stomal sleeve **50** has a first end portion **52** that is secured to the first tissue contact surface **36** of the anvil head **32** at a location radially inwardly of the annular array of staple deforming pockets **38** and a second end portion **54** that is secured to a distal face **32a** of the anvil head **32**.

Referring to FIG. 7, after tissue has been drawn into the tissue gap "G" (FIG. 6), the stapling device **10** is approximated to clamp tissue between the cartridge assembly **18** and the anvil assembly **20**. More specifically, when the tool assembly **16** is moved to the approximated position, tissue including a portion of the vessel portion "IC" is clamped between the tissue contact surface **36** of the anvil head **32** and the tissue contact surface **40** of the staple cartridge assembly **18a**. As shown, the first end portion **52** of the stomal sleeve **50** is also clamped between the tissue and the contact surface **36** of the anvil head **32**.

When the stapling device **10** (FIG. 1) is fired, a pusher **80** of the stapling device **10** is advanced through the cartridge assembly **18** to drive staples **26** (FIG. 6) from the staple

6

cartridge **18a** through the tissue including the vessel portion "IC". Simultaneously, the annular knife **28** is advanced towards the anvil head **32** to cut the tissue and the first end portion **52** of the stomal sleeve **50** radially inwardly of the staple deforming pockets **38**. When the annular knife **28** cuts through the first end portion **52** of the stomal sleeve **50**, the first end portion **52** of the stomal sleeve **50** is separated from the anvil head **32** and stapled to the vessel portion "IC" and surrounding tissue (FIG. 8).

Referring to FIG. 8, after the tool assembly **16** of the stapling device **10** is unapproximated to release the clamped tissue from between the cartridge assembly **18** and the anvil assembly **20**, the stapling device **10** (FIG. 1) can be withdrawn in the direction indicated by arrows "A" in FIG. 8 to withdraw the tool assembly **16** from the stoma **70**. As discussed above, the second end portion **54** of the stomal sleeve **50** is attached to the distal face **32a** of the anvil head **32**. Thus, as the tool assembly **16** is withdrawn from the stoma **70**, the second end portion **54** of the stomal sleeve **50** is pulled through the stoma **70** to a position externally of the stoma **70** such that the stomal sleeve **50** defines an internal liner from the stapling location **90** within the vessel portion "IC" through the stoma **70**.

Referring also to FIG. 10, when the stomal sleeve **50** is positioned externally of the stoma **70**, the second end portion **54** of the stomal sleeve **50** can be separated from the anvil head **32** to define an opening or mouth **92** adjacent the second end portion **54** of the stomal sleeve **50**. In embodiments, the second end portion **54** of the stomal sleeve **50** is closed and is separated from the anvil head **32** by cutting the second end portion **54** using a scissor **96** (FIG. 9) along a cut line "CL". As illustrated, in this position, the stomal sleeve **50** provides an insulative barrier from a position within the vessel portion "IC" through the stoma **70**. It is also envisioned that the second end portion **54** of the stomal sleeve **50** may define an opening and be secured to the anvil head **32** by an adhesive. In this embodiment, instead of cutting the second end portion **54** of the stomal sleeve **50**, the second end portion **54** of the stomal sleeve **50** can be separated from the distal surface **32a** of the anvil head **32** by pulling the second end portion **54** in a direction away from the anvil head **32** to disengage the second end portion **54** from the adhesive on the anvil head **32**. Other methods of releasably securing the second end portion **54** of the stomal sleeve **50** to the anvil head **32** are envisioned.

Persons skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments. It is envisioned that the elements and features illustrated or described in connection with one exemplary embodiment may be combined with the elements and features of another without departing from the scope of the present disclosure. As well, one skilled in the art will appreciate further features and advantages of the disclosure based on the above-described embodiments. Accordingly, the disclosure is not to be limited by what has been particularly shown and described, except as indicated by the appended claims.

What is claimed is:

1. A stapling device comprising;

a tool assembly including an anvil assembly and a shell assembly, the anvil assembly having an anvil shaft and an anvil head having an annular configuration supported on the anvil shaft, the anvil head defining a first tissue contact surface and including an annular array of staple deforming pockets positioned about the first tissue contacting surface, the shell assembly including

a staple cartridge defining a second tissue contact surface having an annular array of staple receiving pockets, the tool assembly being movable from an unapproximated position in which the anvil assembly is spaced from the staple cartridge to an approximated position in which the tissue contacting surfaces of the anvil assembly and the staple cartridge are in closer juxtaposed alignment; and

a stomal sleeve having a tubular configuration, the stomal sleeve having a first end portion secured to the first tissue contacting surface of the anvil head radially inwardly of the annular array of staple deforming pockets with a first adhesive and a second end portion secured to a distal surface of the anvil head with a second adhesive.

2. The stapling device of claim 1, wherein the shell assembly includes an annular knife that is movable from a retracted position recessed within the staple cartridge to an advanced position in contact with the anvil head.

3. The stapling device of claim 2, wherein in the advanced position of the annular knife, the annular knife is positioned to engage the stomal sleeve at a location adjacent the first end portion.

4. The stapling device of claim 3, wherein the second end portion of the stomal sleeve is closed.

5. The stapling device of claim 4, wherein the first end portion of the stomal sleeve defines an opening.

6. The stapling device of claim 3, wherein the stomal sleeve is formed from a non-degradable, bio-compatible, pliable material.

7. The stapling device of claim 5, wherein the stomal sleeve is formed from a polymeric material.

* * * * *